

**REMARKS**

Claims 9, 14, 20-23, and 30 are pending and rejected. Claims 6-8, and 16-19 have been cancelled without prejudice. Applicants reserve the right to prosecute subject matter of the canceled claims in subsequent patent applications.

Claims 9, 20-21 and 23 have been amended to add a comma before "wherein."

Claim 19 has been amended to be independent to recite a transgenic plant comprising a nucleic acid encoding a microbial  $\beta$ -1,4-endoglucanase, wherein said nucleic acid is stably integrated into a nuclear or plastid genome of the plant and is under control of a chemically-inducible promoter, and wherein said chemically-inducible promoter is one of a PR-1, PR-1a, PR-2, PR-3, PR-4, and PR-5 promoter. Support is in the specification and in claims 6-9 and 16.

Claims 21 and 22 have been amended to depend upon amended claim 9, instead of cancelled claim 6.

Claim 23 has been amended to depend upon amended claim 9 instead of cancelled claim 7.

Claim 30 has been amended to depend upon amended claim 9 instead of cancelled claim 13 and to recite said microbial source instead of "microorganism".

No new matter has been added by this amendment.

**Claim Objections**

Claims 8-9, 16-17, 19-21 and 23 are objected to because there should be a comma before "wherein." Claims 8, 16-17 and 19 have been cancelled, making this objection moot. Claims 9, 20-21 and 23 have been amended to insert the comma.

**Claim Rejections under 35 USC 112 , second paragraph**

Claims 8-9, 14-15 and 30 are rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Claim 30 is dependent upon canceled claim 13, and other claims are dependent upon claim 30.

Applicants have amended claim 30 to depend upon claim 9, which should correct the incorrect dependency on a cancelled claim. Also, claims 14-15 and 8 have been cancelled, making this rejection moot. Applicants respectfully request withdrawal of this rejection.

**Claim Rejection under 35 USC 112, first paragraph**

Claims 6-9, 14, 16-17, 19-23 and 30 are rejected under 35 USC 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed.

Applicants respectfully disagree with this rejection.

The legal standard for meeting the written description requirement under section 112, first paragraph, is whether “the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111,1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

The patent application need not teach what is already known to those of ordinary skill in the art (*Hyatt v. Boone*, 146 F.3d 1348, 47 USPQ2d 1128(Fed. Cir. 1998) citing *In re Eltgroth*, 419 F.2d 918, 921, 164 USPQ 221, 223 (CCPA 1970).

Applicants respectfully disagrees with a statement in the Office Action on page 4 where it states: "the specification only teaches one nucleic acid encoding a fungal  $\beta$ -1,4-endoglucanases, and nucleic acid encoding a fungal  $\beta$ -1,4-endoglucanases from only one *Thermomonospora* species" (emphasis added). The specification specifically describes three endoglucanases from the bacteria, *Thermomonospora fusca*, E1, E2 and E5 on page 14 of the specification. Further, the references cited on page 15 describe additional endoglucanases (cellulases) from bacterial and fungal sources that were available to those of ordinary skill in the art at the time of the filing of this application.

The specification as filed provides references describing several bacterial and fungal endoglucanases known to those in the art at the time the application was filed. These endoglucanases were available to those in the art. In particular, on pages 14-15 there list several sources of "cellulase genes for transformation into plants". The specification lists the *T. fusca* E1, E2 and E5 genes in particular set forth in references (GeneBank Accession No. L20094, Jung et al. 1993), GenBank Accession no. M73321, Ghangas et al., 1988; Lao et al., 1991; and GenBank Accession No. L01577; Collmer and Wilson, 1983; Lao et al. 1991, respectively. The specification continues and states, "other cellulase genes may be transformed into plants according to the present invention as well, including all of the cellulase genes disclosed in the following references: Collmer et al. (1983) Bio/Technology 1:594-601; Ghanges et al. (1988) Appl. Environ. Microbiol. 54:2521-2526; Wilson (1992) Crit. Rev. Biotechnol. 12:45-63; Jung et al. (1993) Appl. Environ. Microbiol. 59:3032-3043; Lao et al. (1991) J. Bacteriol. 173:3397-3407; and Thomas et al., "Initial Approaches to Artificial Cellulase Systems for Conversion of Biomass to Ethanol"; Enzymatic Degradation of Insoluble Carbohydrates, J.N. Saddler and M.H. Penner, eds., ACS Symposium Series 618:208-36, 1995, American Chemical Society, Washington, D.C. These include, but are not limited to, endoglucanases, exoglucanases, and  $\beta$ -D-glucosidases derived from microorganisms such as bacteria and fungi."

In particular, Wilson (1992, Crit. Rev. Biotechnology 12:45-63) on page 46, col. 1, describes two cellulase genes isolated from *Thermomonospora curvata* (subsequently reclassified as *T. fusca*); five different cellulase genes from *Microbispora bispora* (citing Waldron et al.) and one cellulase from the fungus *Streptomyces* and one cellulase from the *Micromonospora*. Within this reference on page 56, col. 2, the authors compare the recently cloned cellulases with previously discovered cellulases from the bacteria *Pseudomonas fluorescens*, *Cellulomonas fimi* endoglucanase and *Bacillus* cellulase.

Lao et al., (1991) J. Bacteriol. 173:3397-3407 describes three endoglucanase genes from *T. fusci* (E2, E5 and N-terminal of E4).

Thomas et al., (1995) ACS Symposium Series 618:208-236 describes cellulases isolated from a variety of sources such as the fungus, *Trichoderma reesei* and the

bacteria *Acidothermus cellulolyticus* and *Thermotoga meapolitana* (page 209, 3<sup>rd</sup> paragraph). Further, on page 210, the article states: "more than 60 cellulolytic fungi have been reported . . . representing the soft-rot, brown-rot, and white-rot fungi" (citations omitted). Also a review of the literature found 46 unique bacterial producers of cellulases including the genera *Thermomonospora*, *Microbispora*, *Acidothermus*, *Pseudomonas*, *Therotoga*, *Erwinia*, and *Acetivibrio*.

Additionally, various genetic databases, such as Genebank, were available at the time of the filing of this patent application that listed known endoglucanase sequences. For example, endoglucanase genes were isolated and identified in the three fungi *Humicola insolens* (Genbank Accession no. X76046; published in Mol. Gen. Genet. (1994) 243:253-260); *Penicillium janthinellum* (Genbank Accession no. X89564; published in Curr. Genet. (1996) 29:490-495); and *Hypocrea jecorina* (Genbank Accession no. Z33381; published in Mol. Microbial. (1994) 13:219-228) (copies attached as Exhibits 1-3).

Given all these references and sources of endoglucanases from fungi or bacteria, one of ordinary skill in the art would be able to identify other sources of fungal and bacterial cellulases/endoglucanases beyond those of *T. fusci* used specifically in the examples of this application. It is not necessary in a patent application to describe information and facts known to those skilled in the art nor list every possible endoglucanase known at the time of the invention. The application as filed provides sufficient written description to identify other endoglucanases from bacteria and fungi to those of ordinary skill in the art.

Applicants submit these remarks and amendments overcome this rejection and request its withdrawal.

#### **Claim Rejection under 35 USC 112, first paragraph**

Claims 6-9, 14, 16-17, 19-23 and 30 are rejected under 35 USC 112, first paragraph, as allegedly not enabled by the specification for all β-1,4-endoglucanases. The specification is considered enabled for *T. fusca* β-1,4-endoglucanase.

Applicants respectfully disagree with this rejection.

Enablement of a disclosure “is not precluded by the necessity for some experimentation such as routine screening.” In re Wands, 858 F.2d 731, 736-7 (Fed. Cir. 1988) (citations omitted). The experimentation necessary must not be undue. Id. At 737. Undue experimentation is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. Fields v. Conover, 170 USPQ 276, 279 (CCPA 1971). The factors that can be considered in determining whether an amount of experimentation is undue have been listed in Wands, 858 F.2d at 737. Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, the amount of pertinent literature and the level of skill in the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. Id.

The relevant inquiry for determining whether the scope of the claims is commensurate with the specification is “whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims.” In re Moore, 439 F.2d 1232, 1236 (CCPA 1971) (emphasis added). “A patent need not teach, and preferably omits, what is well known in the art.” Hybridtech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), cet. Denied, 480 U.S. 947 (1987).

While predictability of the art can be considered in determining whether an amount of experimentation is undue, mere unpredictability of the result of the experiment is not a consideration. Indeed, the Court of Customs and Patent Appeals has specifically cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue (see In re Angstadt, 190 USPQ 214 (CCPA 1976)).

Enablement doesn’t require detailed description of every possible embodiment.

There is no requirement in section 112, first paragraph, that the specification provide a detailed description of every possible embodiment covered by the claims. The Examiner is respectfully referred to the controlling opinion in In re Goffe, 191

USPQ 429, 431 (1976), which makes clear that a claim may cover embodiments not actually reduced to practice prior to the filing date of the application:

For all practical purposes, the Board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute.

However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specific for "preferred" materials in a process . . . would not serve the constitutional purpose of promoting progress in the useful arts.

The claimed method calls for integration into plant cells of a DNA construct encoding a  $\beta$ -1,4-endoglucanase. The regulatory regions instruct the plant cell to transcribe the region of the DNA coding for the endoglucanase. The critical aspect of the method is not the nature of the endoglucanase, but rather the use of appropriate regulatory sequences which would function in the host plant cells to express the coding sequence. By using appropriate regulatory sequences, endoglucanases can be produced in plants cells as exemplified by the production of *T. fusca* endoglucanase.

In line with the holding in Goffe, supra, it does not serve the constitutional purpose of promoting progress in the useful arts if others may take Applicants' example of production of the *T. fusca* endoglucanase in a plant cell and substitute the coding sequence from a structural gene for another endoglucanase to obtain expression of that endoglucanase. The Examiner is fully aware that substituting one structural gene for another in an expression cassette is within the knowledge of one of ordinary skill in the art and does not require "undue experimentation."

Many bacterial and fungal endoglucanases are described in the reference cited in the specification. The specification also describes how to make expression cassettes and express an exemplary endoglucanase in the plastid of plant cells. Given the descriptions in the specification, one of ordinary skill in the art would be able to

substitute an endoglucanase of *T. fuscii* and replace it with another endoglucanase from a different fungal or bacterial source without any undue experimentation.

Applicants submit these remarks and amendments overcome this rejection and request its withdrawal.

### **Claim Rejection under 35 USC § 103**

Claims 6-8, 14-17, 19, 21-23 and 30 are rejected under 35 USC § 103(a) as allegedly being unpatentable over Van Ooyen et al. (US Patent No. 5,705,375) in view of Lao et al. (1991). Claims 9 and 20 are considered free of the prior art.

Applicants respectfully disagree with this rejection. However, in order to advance prosecution of certain embodiments of the invention, claims 9 and 20 have been amended to be independent, and claims 21-23 have been amended to be dependent upon claim 9. Claims 6-8 and 16-17 have been cancelled without prejudice, making this rejection moot. These amendments should overcome this rejection, and applicants respectfully request its withdrawal.

### **CONCLUSION**

Applicants point out that the above remarks and amendments overcome the rejections. Reconsideration of the application and allowance of all pending claims is earnestly solicited.

Should the Examiner wish to discuss any of the above in greater detail or deem that further amendments should be made to improve the form of the claims, the Examiner is invited to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,

Syngenta Biotechnology, Inc.  
3054 E. Cornwallis Road  
Research Triangle Park, NC 27709-2257

Date: 2/14/06

Mary Kakefuda  
Mary Kakefuda  
Attorney for Applicants  
Registration No. 39,245  
Telephone: 919-765-5071